

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Bell, et al. Atty. Ref.: 18003
Appl. No.: 09/664,444 Group Art Unit: 1645
Filed: September 18, 2000 Examiner: Robert A. Zeman
Conf. No.: 4773 Customer No.: 31976
For: ONCOLYTIC VIRUS



* * * * *

December 23, 2003

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Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Examiner is directed to the documents listed on the enclosed Form PTO-1449. A copy of each listed document is enclosed.

This Statement is being filed in conjunction with a Request for Continued Examination for the above-mentioned application.

It is believed that no fee is required in connection with the filing of this Statement. If any fee is required, the Commissioner is hereby authorized to charge the amount of such fee to Deposit Account No. 50-1677.

Respectfully submitted,

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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1 of 10

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Application Number	09/664,444
Filing Date	September 18, 2000
First Named Inventor	John C. Bell
Group Art Unit	1645
Examiner Name	Robert A. Zeman
Attorney Docket Number	18003

NON PATENT PUBLICATIONS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue numbers, publisher, city and/or country where published	T ²
		Kim, et al., "Replicating Viruses as Selective Cancer Therapeutics", <i>Molecular Medicine Today</i> , pages 515-521, December 1999.	
		Heise, et al., "Onyx-015, an E15-glyceraldehyde-3-phosphate dehydrogenase-expressing adenovirus, causes tumor-specific cytolysis and antitumor efficacy that can be augmented by standard chemotherapeutic agents", <i>Nature Medicine</i> , Vol. 5, No. 6, pages 640-646, June 1996.	
		Zhang, et al., "Treatment of a Human Breast Cancer Xenograft with an Adenovirus Vector Containing an Interferon Gene Results in Rapid Regression Due to Tissue Oncolytic and Gene Therapy", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 93, pages 4512-4516, April 1996.	
		Katze, "Regulation of the Interferon-induced PKR can viruses copy?", <i>Trends in Microbiology</i> , Vol. 3, No. 2, pages 75-78, February 1995.	
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		Chou, et al., "Association of a M1-50,000 phosphoprotein with protein kinase PKR in cells exhibiting enhancing phosphorylation of translation complex virus 4f", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 92, pages 10514-10520, November 1995.	
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		Pelizzetti, et al., "Human Cancer Cell Lines Express a Negative Transcriptional Regulator of the Interferon Regulatory Factor Family of DNA Binding Proteins", <i>Molecular and Cellular Biology</i> , Vol. 14, No. 2, pages 1477-1486, February 1994.	
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		Liu, et al., "Interferon System Defects in Human Malignant Melanoma", <i>Cancer Research</i> , Vol. 55, pages 4088-4104, September 15, 1995.	
		Mashida, et al., "Effectiveness of Nucleosides on Interferon Production and Development of Antiviral State Induced by Poly I-Poly C", <i>Microbiologia Immunologica</i> , Vol. 23 (7), pages 643-650, 1979.	

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		Tenska, et al., "Cellular Commitment to Oncogene-Induced Transformation or Apoptosis is Dependent on the Transcription Factor IRF-1", Cell, Vol. 77, pages 829-839, June 17, 1994.	
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		James, et al., "Chromosome 9 Deletion Mapping Reveals Interferon α and Interferon β -1 Gene Deletions in Human Glioblastoma", Cancer Research, Vol. 51, pages 1684-1688, March 15, 1991.	

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		Arroyo, et al., "Active specific immunotherapy with vaccinia colon oncolysate enhances the immunomodulatory and antitumor effects of interleukin-2 and interferon α in a murine hepatic metastasis model", <i>Cancer Immunology Immunotherapy</i> , Vol. 31, pages 365-374, 1990.	
		Zhang, et al., "High-efficiency gene transfer and high-level expression of wild-type p53 in human lung cancer cells mediated by recombinant adenovirus", <i>Cancer Gene Therapy</i> , Vol. 1, No. 1, pages 5-13, 1994.	
		Korth, et al., "Cloning, expression, and cellular localization of the oncogenic 58-kDa inhibitor of the RNA-activated human and mouse protein kinase", <i>Gene</i> , Vol. 170, pages 181-188, 1996.	
		Barber, et al., "The 35-kilodalton inhibitor of the interferon-induced double-stranded RNA-activated protein kinases is tetratricopeptide repeat protein with oncogenic properties", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 91, pages 4278-4282, May 1994.	
		Mattews, et al., "Reovirus-Associated RNA and Translation Control", <i>Journal of Virology</i> , Vol. 65, No. 11, pages 5657-5662, Nov. 1991.	
		Irrfan, et al., "Inhibitory activity for the interferon-induced protein kinase is associated with the reovirus serotype...protein", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 85, pages 7887-7891, November 1988.	
		Tanaka, et al., "Immunotherapy of Vaccinia Colon Oncolysate Prepared with Interleukin-2 Gene-Encoded Vaccinia Virus and Interferon- α Increases the Survival of Mice Bearing Syngeneic Colon Adenocarcinoma", <i>Journal of Immunotherapy</i> , Vol. 16, No. 4, Pages 283-293, 1994.	
		Gsatery, et al., "Altered Veterinary Virus Vaccine for the Treatment of Cancer", <i>Cancer Detection and Prevention</i> , Vol 17, No. 6, pages 619-627, 1993.	
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		Lorenzen, et al., "Newcastle Disease Virus as an Antineoplastic Agent: Induction of Tumor Necrosis Factor- α and Augmentation of Its Cytotoxicity", <i>Journal of the National Cancer Institute</i> , Vol. 80, No. 16, pages 1305-1312, October 19, 1988.	

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		Renhard, et al., "Newcastle Disease Virus Selectively Kills Human Tumor Cells", Journal of Surgical Research, Vol 52, pages 448-453, 1992.	
		Eaton, et al., "Contribution of Antiviral Immunity to Oncolysis by Newcastle Disease Virus in a Murine Lymphoma", Journal of the National Cancer Institute, Vol. 39, No. 6, December 1967.	
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		Bart, et al., "Role of Interferon in the Anti-Melanoma Effects of Poly(I).Poly(C) and Newcastle Disease Virus", Nature New Biology, Vol. 245, No. 147, pages 228-230, October 24, 1973.	
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		Murray, et al., "Viral Oncolysate in the Management of Malignant Melanoma", Cancer, Vol. 40, No. 2, pages 680-686, August 1977.	
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		Bohle, et al., "Postoperative Active Specific Immunization in Colorectal Cancer Patients with Virus-Modified Autologous Tumor-Cell Vaccine", Cancer, Vol. 56, No. 7, pages 1517-1523, October 1, 1990.	
		Eaton, et al., "Autoimmunity Induced by injection of Virus-Modified Cell Membrane Antigens in Syngeneic Mice", Infection and Immunity, Vol. 15, No. 1, pages 383-392, January 1977.	

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		Wheelock, et al, "Observation on the Repeated Administration of Viruses to a Patient with Acute Leukemia", The New England Journal of Medicine, Vol. 271, No. 13, pages 645-651, September 24, 1964.	
		Castany, "Viruses in the Treatment of Cancer", The Lancet, page 622, October 2, 1971.	
		Kenney, et al, "Viruses as Oncolytic Agents: A New Age for "Therapeutic" Viruses?", JNCL Editorial Issue 16, pages 1-3, June 20, 1997.	
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		Mantouze, "Novel Treatment Approach for Malignant Brain Tumors Developed at Georgetown", Georgetown University Medical Center, pages 1-6, October 1995.	
		Mineta, et al, "Attenuated multi-mutated herpes simplex virus-1 for the treatment of malignant gliomas", Nature Medicine, Vol. 1, No. 9, pages 535-542, September 1995.	
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		Ganly, et al, "Phase I trial of intratumoral injection with an E1B-attenuated adenovirus, ONYX-015, in patients with recurrent p53+ head and neck cancer", Proceedings of ASCO, Vol. 16, page 433a, 1997. Abstract 1362.	
		Kim, et al, "ONYX-015, A selectively replicating adenovirus, has antitumoral activity following IV administration alone and in combination with chemotherapy", Proceedings of ASCO, Vol. 16, page 433a, 1997. Abstract 1564.	
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		Field, et al., "The pathogenicity of thymidine kinase-deficient mutants of herpes simplex virus in mice", J. Hyg., Camb., Vol. 81, pages 267-277, 1978.	
		Springer, et al., "Attenuated revovirus type 3 strains generated by selection of haemagglutinin antigenic variants", Nature, Vol. 297, pages 88-90, May 6, 1982.	
		Goldstein, et al., "Factor(s) Presented in Herpes Simplex Virus Type 1-Infected Cells Can Compensate for the Loss of the Large Subunit of the viral Ribonucleotide Reductase: Characterization of an ICP6 Deletion Mutant", Virology, Vol. 166, pages 41-51, 1988.	
		Perkins, et al., "Deletion of 55 Open Reading Frames from the Termini of Vaccinia Virus", Virology, Vol. 180, pages 406-410, 1991.	
		McGehee, M.L., "In Vivo Behavior of Genetically Engineered Herpes Simplex Viruses R7017 and R7020. II. Studies in Immunocompetent and Immunocompetent/Owl Monkeys (Aotus trivirgatus)", The Journal of Infectious Disease, Vol. 162, pages 313-312, 1990.	
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		Howard, et al., "Reovirus-Mediated Gene Transfer of the Human...Gene: A Therapy for Cancer", Annals New York Academy of Sciences, Duke University Medical Center, pages 167-187.	
		Suskind, et al., US Dept. of Health, Education & Welfare, N.I.H., National Institute of Allergy and Infectious Disease, and N.C.I. Bethesda, Md., "Viral Agents Oncolytic for Human Tumors in Heterologous Host: Oncolytic Effect of Coxsackie B. Viruses, pages 309-318, October 29, 1956.	
		Bleomycin, et al., "Regression of Burkitt's Lymphoma...Association with Measles Infection" The Lancet, pages 105-106, July 10, 1971.	
		Pasquinelli, et al., "Possible Effect of Measles on Leukemia", The Lancet, page 136, January 16, 1971.	
		Greco, "Measles and Leukaemia", The Lancet, Pages 307-308, February 20, 1974.	
		Shingu, "Therapeutic effects of bovine enterovirus infection on rabbits with experimentally induced adult T cell leukaemia", Journal of General Virology, Vol. 72, pages 2031-2034, 1991.	
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		Reitzsiedel, et al., "The Use of APC3 Virus as a Cancercidal Agent", Cancer, Vol. 10, Pages 577-580, May-June 1957.	
		Smith, et al., "Studies on the Use of Viruses in the Treatment of Carcinoma of the Cervix", Cancer, Vol. 9, pages 1211-1218, November -December 1956.	
		Rukavishnikova, et al., "Some Immunological Mechanisms of the Influenza Virus Antitumour Effect", Acta Virol., Vol. 20, pages 387-394, 1976	
		Varma, et al., "Gene therapy-promises, problem and prospects", Nature, Vol. 389, pages 239-242, September 18, 1997.	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

8 of 10

Application Number	09/664,444
Filing Date	September 18, 2000
First Named Inventor	John C. Bell
Group Art Unit	1645
Examiner Name	Robert A. Zeman
Attorney Docket Number	18003

NON PATENT PUBLICATIONS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue numbers, publisher, city and/or country where published	T ²
/RAZ/		Kalvakolanu, et al., "Differentiation-dependent activation of interferon-stimulated gene factors and transcription factor NF- κ B in mouse embryonal carcinoma cells", Proc. Natl. Acad. Sci. USA, Vol. 90, pages 3167-3171, April 1993.	
/RAZ/		Foy, et al., "In Vivo CD40-gp39 Interactions are Essential for Thymus-Dependent Humoral Immunity. III. Prolonged Suppression of the Humoral Immune Response by an Antibody to the Ligand for CD40(gp39)", J. Exp. Med., Vol. 178, pages 1567-1575, November 1993.	
/RAZ/		Blaese, et al., "In situ Delivery of Suicide Genes for Cancer Treatment", European Journal of Cancer, Vol. 30A, No. 8, Pages 1190-1193, 1994.	
/RAZ/		Zhang, et al., "Gene Therapy with an adeno-associated virus carrying an Interferon gene results in tumor growth suppression and regression", Cancer Gene Therapy, Vol. 3, No.1, pages 31-38, 1996.	
/RAZ/		Peplinski, et al., "Prevention of Murine Breast Cancer by Vaccination with Tumor Cells Modified by Cytokine-Reproducing Recombinant Vaccinia Viruses", Annals of Surgical Oncology, Vol. 3, No. 1, pages 15-23.	
/RAZ/		Cotran, et al., "Kinetics of Tumor Cell Growth", Robbins Pathologic Basis of Disease, 4th Edition, page 251.	
/RAZ/		Schloer, et al., "Relationship of Plaque Size and Virulence for Chickens for 14 Representative Newcastle Disease Virus Strains", Journal of Virology, Vol. 2, No. 1, Pages 40-47, January 1968.	
/RAZ/		Tait, et al., "A Phase I Trial of Retroviral BRCA1sv Gene Therapy in Ovarian Cancer", Clinical Cancer Research, Vol. 3, pages 1959-1968, November 1997.	
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Examiner Signature	Date Considered
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Sheet 9 of 10

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Application Number	09/664,444
Filing Date	September 18, 2000
First Named Inventor	John C. Bell
Group Art Unit	1645
Examiner Name	Robert A. Zeman
Attorney Docket Number	18003

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		Asada, "Treatment of Human Cancer with Mumps Virus", <i>Cancer</i> , Vol. 34, pages 1907-1928, December 1974.	
		Groves et al., "Chapter 14 Biologic Therapy with Interferon-x and B: Preclinical Studies", <i>Biologic Therapy of Cancer. Principles and Practice</i> , pages 847-864	
		Stamen et al., "Effect of Neuraminidase Pretreatment on the Susceptibility of Normal and Transformed Mammalian Cells to Bovine Enterovirus 201", <i>Nature</i> , Vol. 245, pages 319-320, October 12, 1973.	
		Johlik, "Interferons", Chapter 10, Second Edition, pages 382-410, 1990.	
		Schnell, et al., "Construction of a Novel Virus that Targets HIV-1 Infected Cells and Controls HIV-1 Infection", <i>Cell</i> , Vol. 90, pages 849-857, September 5, 1997.	
		Kirchner, et al., "Adjuvant treatment of locally advanced renal cancer with autologous virus-modified tumor vaccines", <i>World J. Urol.</i> , Vol. 15, pages 471-473, 1995.	
		Murphy, et al., "Virus Taxonomy", <i>Virology</i> , Second Edition, Chapter 2, pages 9-66, 1980.	
		Cestary, "Viruses in the Treatment of Cancer", <i>The Lancet</i> , page 825, October 9, 1971.	
		Haselroth, et al., "The Preferential Cytotoxicity of Recovirus for Certain Transformed Cell Lines", <i>Archives of Virology</i> , Vol. 54, pages 307-315, 1977.	
		Zhang, "Attenuated newcastle disease virus for induction of interferons to combat neoplasm or viral disease", Database Capulus, on STN/Colombus (OH): Chemical Abstract Service, DN 116: 104333, CN 1054192A, Abstract, April 9, 1991.	
		Gresser, et al., "Exogenous Interferon and Inducers of Interferon in the Treatment of Balb/c Mice Inoculated with RC19 Tumor Cells", <i>Nature</i> , Vol. 223, pages 844-845, August 1969.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Application Number	09/664,444	
		Filing Date	September 18, 2000	
		First Named Inventor	John C. Bell	
		Group Art Unit	1645	
		Examiner Name	Robert A. Zeman	
Sheet	10	of 10	Attorney Docket Number	18003

NON-PATENT PUBLICATIONS

Examiner Signature	/Robert Zeman/	Date Considered	05/17/2004
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